

Notice of Allowability	Application No.	Applicant(s)	
	10/767,516	AVELLA ET AL.	
	Examiner	Art Unit	
	Abdel A. Mohamed	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to preliminary amendment filed 11/12/04 and telephonic interview of 6/20/06.
2. ☒ The allowed claim(s) is/are 1-6, 8-13, 15-24 and 26-29.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| <ol style="list-style-type: none"> 1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date <u>11/12/04</u> 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>20060621</u>. 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other _____. |
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DETAILED ACTION

ACKNOWLEDGMENT OF PRELIMINARY AMENDMENT, IDS, STATUS OF THE APPLICATION AND CLAIMS

1. The preliminary amendment filed 01/29/04 and the information disclosure statement (IDS) and Form PTO-1449 filed 11/12/04, respectively are acknowledged, entered and considered. In view of Applicant's request claims 30-32 have been canceled. Claims 1-29 are now pending in the application.

EXAMINER'S AMENDMENT

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

3. Authorization for this examiner's amendment was given in a telephone interview with Patrick G. Gattari on 6/20/06.

4. The application has been amended as follows:

Replace the claims as follows.

1. (Amended) A method for producing a substantially tetramer free hemoglobin solution comprising:

a) polymerizing hemoglobin in solution;

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b) heat treating the polymerized hemoglobin in solution above about 45 °C for at least about 24 hours;

c) removing tetramer from the polymerized hemoglobin in solution.

2. (Original) The method of claim 1 wherein the hemoglobin is derived from mammalian blood.

3. (Original) The method of claim 2 wherein the mammalian blood is human blood and the hemoglobin is pyridoxylated.

4. (Original) The method of claim 1 wherein the hemoglobin is derived from bovine blood.

5. (Original) The method of claim 1 wherein the hemoglobin is polymerized with glutaraldehyde.

6. (Original) The method of claim 1 wherein the tetramer is removed by filtration.

7. (Canceled)

8. (original) The method of claim 1 wherein the tetramer concentration at the completion of step (c) is less than about 1.0% of total hemoglobin in the solution.

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9. (Original) The method of claim 1 wherein the tetramer concentration at the completion of step (c) is less than about 0.3% of total hemoglobin in the solution.

10. (Original) The method of claim 1 further comprising, in addition to step (c), removing tetramer from the solution prior to the heat treating.

11. (Original) The method of claim 10 wherein tetramer is removed from the solution prior to the heat treating until the solution is essentially tetramer free.

12. (Original) The method of claim 11 wherein the tetramer concentration prior to the heat treating is less than about 1.0% of total hemoglobin in the solution.

13. (Original) The method of claim 12 wherein the tetramer concentration prior to the heat treating is less than about 0.3% of total hemoglobin in the solution.

14. (Canceled)

15. (Amended) A method for stabilizing an essentially tetramer free polymerized hemoglobin solution comprising treating the polymerized hemoglobin solution to partially degrade the polymerized hemoglobin to tetramer and removing the tetramer from the solution, wherein the treating comprises aging the solution either for longer than one year or until the concentration of tetramer in the solution is above about 1%, or heating

the solution above about 45 °C for at least about 24 hours.

16. (Original) The method of claim 15 wherein the treating comprises aging the solution.

17. (Original) The method of claim 15 wherein the treating comprises aging the solution until the tetramer concentration is above about 1.0% of the total hemoglobin in solution.

18. (Original) The method of claim 15 wherein the treating comprises heating the solution.

19. (Original) The method of claim 15 wherein the treating comprises heating the solution until the tetramer concentration is above about 1.0% of the total hemoglobin in solution.

20. (Original) The method of claim 15 wherein the hemoglobin is derived from mammalian blood.

21. (Original) The method of claim 15 wherein the mammalian blood is human blood and the hemoglobin is pyridoxylated.

22. (Original) The method of claim 15 wherein the hemoglobin is derived from bovine blood.

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23. (Original) The method of claim 15 wherein the hemoglobin is polymerized with glutaraldehyde.

24. (Original) The method of claim 15 wherein the tetramer is removed by filtration.

25. (Canceled)

26. (Amended) A method for producing a stabilized, polymerized hemoglobin solution comprising:

- a) producing a polymerized hemoglobin solution;
- b) removing tetramer from the polymerized hemoglobin solution to produce a substantially tetramer free polymerized hemoglobin solution;
- c) aging the polymerized hemoglobin solution for longer than one year or until the concentration of tetramer in the solution is above about 1%; and
- d) removing the ~~elaborated~~ tetramer that elaborated during the aging.

27. (Original) The method of claim 26 wherein the aging comprises storing the hemoglobin solution until the tetramer concentration is greater than about 1.0% of total hemoglobin.

28. (Original) The method of claim 26 wherein the aging comprises storing the hemoglobin solution until the tetramer concentration is greater than about 3.0% of total

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hemoglobin.

29. (Original) The method of claim 26 wherein the aging comprises storing the hemoglobin solution for longer than one year.

30-32. (Canceled).

REASONS FOR ALLOWANCE

5. The following is an examiner's statement of reasons for allowance: The closest prior art is WO 97/35883 cited by Applicant which teaches a method for producing a substantially tetramer free hemoglobin solution from human or other mammalian sources which includes bovine comprising the steps of polymerizing hemoglobin solution, removing tetramer from the polymerized hemoglobin solution and resulting in stabilized product having a substantially tetramer free hemoglobin solution thereof. However, the prior art of record either singularly or in combination does not teach or suggest the instantly claimed invention's step(s) of heat treating the polymerized hemoglobin in solution above about 45 °C for at least about 24 hours and aging the polymerized hemoglobin solution for longer than one year or until the concentration of tetramer in the solution is above 1% in the manner claimed in the instant invention.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably

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accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."


CONCLUSION AND FUTURE CORRESPONDANCE

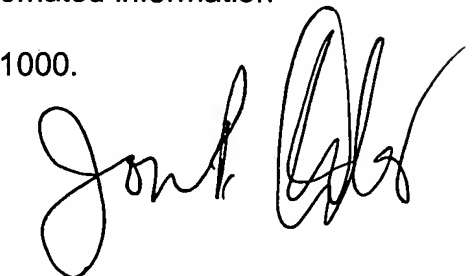
6. Claims 1-6, 8-13, 15-24, and 26-29 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (571) 272 0955. The examiner can normally be reached on First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tsang Cecilia can be reached on (571) 272 0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

 Mohamed/AAM
June 21, 2006



Jon Weber
Supervisory Patent Examiner